

### **REMARKS**

Claims 1, 2, 4-8, 11, 12, 20, 23, 24, 40 and 41 are pending in the present application. Applicant has amended claim 4. Accordingly, each of the pending claims remain at issue in the present application.

In the office action the Examiner rejected claims 1-2, 4-8, 11-12, 20, 23-24 and 40-41 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,562,001 to Lebel et al. ("Lebel"). The Examiner also provisionally rejected claims 1-2, 4-8, 11-12, 20, 23-24 and 40-41 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of co-pending Application No. 10039751. Applicant respectfully traverses these rejections.

### **The Present Office Action is a Non-Final Office Action**

As acknowledged by the Examiner, the finality of the present office action is erroneous and has been withdrawn. The present action was necessitated solely by a new search and resulting new art cited by the Examiner, and was not necessitated by the Applicant as the Applicant did not amend any claims in response to the prior action.

### **Rejection of Claims Under 35 U.S.C. §§ 102(e) by Lebel**

The Examiner rejected claims 1-2, 4-8, 11-12, 20, 23-24 and 40-41 under 35 U.S.C. §102(e) as being anticipated by Lebel. The Examiner stated that paragraphs 23, 40, 55, 63, 72, 77, 119, 298 and 289 teach the claimed subject matter. Applicant respectfully traverses this rejection.

In order for a reference to act as a § 102 bar to patentability, the reference must teach each and every element of the claimed invention. *Kalman v. Kimberly-Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983). Applicant respectfully submits Lebel does not disclose each and every element of any independent claim, and as such the claims are not anticipated by Lebel. Further, Applicant respectfully states that the disclosure of Lebel is so distinct from Applicant's claimed subject matter that it also does not render any of the claims as being obvious.

Specifically, claim 1 recites a a sensor coupled to a patient to receive information from the patient concerning the physiological condition of the patient, and the information being transferred

from the sensor to the control algorithm. Similarly, independent claim 4 recites “the controller dynamically processing a signal received from a sensing device connected to the patient;” independent claim 20 recites “a first sensor coupled to the patient, the sensor receiving a signal from the patient concerning the patient’s physiological condition and transmitting the signal to the processor;” and, independent claim 40 recites “providing a sensor connected to the patient, utilizing the sensor to measure a physiological condition of the patient, [and] transferring the measured condition to the control algorithm and entering the measured condition in the control algorithm.”

Lebel, however, does not disclose: (a) a sensor being coupled to a patient to receive information from the patient concerning the physiological condition of the patient; or (b) information being transferred from the sensor (which is coupled to the patient to receive information from the patient concerning the physiological condition of the patient) to a control algorithm of the medical device. Instead, Lebel merely discloses an implantable medical device, such as an infusion pump, that exchanges messages with an external device via telemetry. Any message transferred between the external controller and the implantable medical device, however, relates to either the functioning of the medical device or to changes in the control parameters received from the clinician operator. This is entirely different and does not begin to anticipate or render obvious Applicant’s claimed subject matter.

The Examiner has identified several different paragraphs in the Lebel reference which allegedly disclose Applicant’s claimed subject matter (i.e., paragraphs 23, 40, 55, 63, 72, 77, 119, 298 and 289). The Applicant has attached copies of these paragraphs as Exhibit A hereto. It is clear that none of the referenced paragraphs discloses: (a) a sensor being coupled to a patient to receive information from the patient concerning the physiological condition of the patient; or (b) information being transferred from the sensor (which is coupled to the patient to receive information from the patient concerning the physiological condition of the patient) to a control algorithm of the medical device. Accordingly, Applicant respectfully submits that Lebel does not anticipate the pending claims.

Further, the Examiner states that “the entire reference” discloses Applicant’s claims. As previously stated in the Reply to Office Action Dated July 30, 2003, this type of rejection is

improper. The MPEP expressly states that the “particular part of the reference relied upon to support the rejection should be identified.” MPEP 706.02(i). By stating “the entire reference,” as support for the rejection the Examiner has merely provided an improper omnibus rejection.

In sum, Applicant respectfully submits that all of the claims are patentable as submitted.

**Provisional Double Patenting Rejection**

If, and when, it is found that a double patenting rejection based on patented claims is valid, Applicant will respond at that time.



U.S. Patent Application No. 10/038,516  
Filed: January 3, 2002  
Page 12

**CONCLUSION**

In view of the present condition of the claims and the foregoing remarks, it is submitted this application is in condition for allowance. Such action is respectfully requested. Further, the Examiner is requested to contact the undersigned if the Examiner has any questions concerning this Response or if it will expedite the progress of this application.

Respectfully submitted,

Dated: April 12, 2004

By: Matthew J. Gryzlo  
Matthew J. Gryzlo, Reg. No. 43,648  
Wallenstein Wagner & Rockey, Ltd.  
311 South Wacker Drive, 53rd Floor  
Chicago, Illinois 60606-6630  
312.554.3300

---

Express Mail Label No. EV443469945US

Date of Deposit: April 12, 2004

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. § 1.10 on the date indicated above and is addressed to: Mail Stop Non-Fee Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.

Sarah J. Goodnight  
Sarah J. Goodnight (198392.1)

RECEIVED  
APR 16 2004  
TECHNOLOGY CENTER

## EXHIBIT A

### Selected Paragraphs From U.S. Patent No. 6,562,001 (US Publication No. 20020058906)

[0023] In a specific variation of the second aspect of the invention the selected function includes the medical device ceasing delivery of medically significant amounts of the drug. In a further variation the predefined period of time is restarted each time a valid message is received from the communication device.

[0040] A thirteenth aspect of the invention provides a medical system that includes (a) an ambulatory medical device (MD) that includes MD electronic control circuitry that further includes at least one MD telemetry system and at least one MD processor that controls, at least in part, operation of the MD telemetry system and operation of the medical device, wherein the medical device is configured to provide a treatment to a body of a patient or to monitor a selected state of the body; and (b) a communication device (CD) that includes CD electronic control circuitry that further includes at least one CD telemetry system and at least one CD processor that controls, at least in part, operation of the CD telemetry system and operation of the communication device, wherein the CD telemetry system sends messages to or receives messages from the MD telemetry system, wherein the medical device, when fully operating, consumes more than about 12 .mu.W and when in a stand by power-saving mode, consumes less than about 100 .mu.W.

[0055] In a specific variation of the fifteenth aspect of the invention at least one MD processor includes a single application specific integrated circuit, or at least one CD processor includes a single application specific integrated circuit.

[0063] In a specific variation of the eighteenth aspect of the invention the medical device automatically switches from the rechargeable battery to the non-rechargeable battery when a voltage of the rechargeable battery falls below a predefined level. In a further variation the medical device automatically switches from the non-rechargeable battery when the voltage of the rechargeable battery rises to a certain level.

[0072] In a specific variation of the twenty-first aspect of the invention the at least two quantities comprise a bolus and a basal quantity. In a further variation the at least one of the at least two quantities is programmed as a delivery rate.

[0077] In a specific variation of the twenty-fourth aspect of the invention the pumping mechanism includes a piston pump having a stroke volume wherein the unit of activation of the pumping mechanism is one stroke volume.

[0119] Still additional aspects of the invention set forth method counterparts to the above system aspects as well as to other functional associations and relationships, and processes that have not been specifically set forth above but will be understood by those of skill in the art from a review of the teachings provided herein.

[0289] Further detail about QFAST.RTM. (Quadrature Fast Acquisition Spread Spectrum Technique) may be found in U.S. Pat. No. 5,559,828, entitled Transmitted Reference Spread Spectrum Communication Using a Single Carrier with Two Mutually Orthogonal Modulated Basis Vectors, by Armstrong, et al.

[0298] The Processor IC has two Synchronous Ser. Interface (SSI) ports 944 and 942. Each interface provides full duplex serial communication ports that operate at about 500 kHz. One of these ports is used for inter-processor communication in the dual processor implantable device. In the external communication device, one port is used for IR based serial communications and the other is used as an interface for the LCD display panel. Each interface port supplies both data and clock. The clock driving the SSI may be enabled or disabled, thus controlling power consumption when the SSI is not needed. A control register is used to turn ON/OFF the SSI.

(198273.1)